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09/554,604	05/31/2000	Andrew J. Dannenberg	CRF D-2165	9421

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1617	20

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Please find below and/or attached an Office communication concerning this application or proceeding.



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### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/554,604  
Filing Date: May 31, 2000  
Appellant(s): DANNENBERG, ANDREW J.

Paper No. 20

Date mailed 10/8/02

Eric S. Spector  
For Appellant

### EXAMINER'S ANSWER

This is in response to the appeal brief filed July 8, 2002.

#### (1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

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**(2) *Related Appeals and Interferences***

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existance of any related appeals and interferences.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

The rejection of claims 3-5 and 17 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

**(8) *ClaimsAppealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent 6,172,096B                    Gregory et al.                    January 19, 2001

US Patent 5,643,933A                    Talley et al.                    July 1, 1997

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 3-5 and 17 are rejected under 35 U.S.C. 103(a)

These rejections are fully set forth in prior office action, paper No. 10.

**(11) Response to Argument**

Appellants' assertion that the examiner erroneously makes overstatement regarding the anti-inflammatory properties of cyclooxygenase-2 inhibitors and their utilities for treating liver diseases is improper. All statement made by examiner in the rejections are solely based on the cited references. Particularly, Gregory states that composition comprising COX-2 is known to be useful for generally treating inflammatory diseases, and many specific inflammatory diseases are given as examples, including biliary cirrhosis. (see column 5, line 42 bridging column 6, line 16).

None of the exhibits presented by appellants are shown in contradiction to the examples given by Gregory. Particularly, none of the exhibits teach or suggest that a cyclooxygenase-2 inhibitor may not be used for treating cirrhosis. It is noted that cirrhosis is a well-known form of alcoholic liver injury. (See, Merck Index, Home Edition, page 623, provided to illustrate the state of art).

Further, appellants must not confuse *primary* biliary cirrhosis with biliary cirrhosis. Biliary cirrhosis may be primary (of unknown origin) or secondary (caused by other etiology). Gregory

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teaches that a composition comprising cyclooxygenase-2 inhibitor is known to be useful for treating biliary cirrhosis generally, not specifically for treating *primary* biliary cirrhosis, as argued by appellant.

Further, appellants appears to accept the fact that cyclooxygenase-2 inhibitor is a known Non-Steroid Anti-Inflammatory Drug (NSAID), as evidenced by those argument been presented. (see page 7, the third and fourth paragraph in the appeal brief).

Appellants allege the “recitation in Gregory et al about the utility is unreliable,” and improperly suggest that Gregory’s patent is not enabled. Since in a patent it is presumed that a process if used by one skilled in the art will produce the product, or result, described therein, such presumption is not overcome by mere showing that it is possible to operate within the disclosure without obtaining the alleged product. (see MPEP 716.07). Gregory et al. teaches cyclooxygenase-2 inhibitor as providing anti-inflammatory benefit for biliary cirrhosis (see column 5, line 65) and appellants’ compounds as cyclooxygenase inhibitor (column 8, lines 64-67).

Seibert et al reference was cited to illustrate that cyclooxygenase-2 inhibitors are different from conventional NSAIDs, and one of ordinary skill in the art would have reasonably expected that cyclooxygenase-2 inhibitors would not possess hepatotoxicity as do conventional NSAIDs. The rejection, as shown in paper No. 10, is not relied on Seibert reference. The cited references teaches the usefulness of cyclooxygenase-2 inhibitor for treating liver disorder, suggesting hepatotoxicity is not a concern in the employment of the examiner cited prior art cyclooxygenase-2 inhibitor. Further, the cited references also disclose that cyclooxygenase-2 inhibitor is known in

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the art to have less side effect than the conventional NSAIDs. (see Gregory column 6, lines 39-49, Tally et al. column 1, lines 28-36).

Appellants' assertion that art as whole does lead away from the invention is not persuasive; contra indication must be specific, clear and available at the time of the claimed invention was made. First, FDA's conclusion in 1982 would have no teaching lead away from the invention since cyclooxygenase-2 inhibitor is generally known for its reduced side effects. (see Gregory column 6, lines 39-49, Tally et al. column 1, lines 28-36). As to the claimed invention, none of the evidence cited by appellants illustrates Gregory et al teaching as "unreliable" or inoperable. Appellants are reminded that the claimed invention is drawn to a method of treating a patient affected with liver disease *comprising* administering to said patient a cyclooxygenase-2 inhibitor. Appellants appear to be arguing a method of treating *consisting of* administering to said patient a cyclooxygenase-2 inhibitor, ignoring the scope claimed invention actually encompassed thereby, and the teaching of the prior arts as whole. Appellants attention is directed to column 6, line 39 bridging column 7, lines 3 in Gregory. Possessing this teaching, it would have been a *prima facie* obvious for one of ordinary skill in the art at the time the claimed invention was made to practice claimed invention, avoid many previously known side effect of cyclooxygenase-2 inhibitor. Further, as set forth by examiner, in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, with such presumption not overcome by mere showing that it is possible to operate within the disclosure without obtaining the alleged product. (see MPEP 716.07). The evidence provided by appellants would not lead the skilled artisan away from the claimed invention, which has been fairly suggested by the cited prior art.

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Appellants' rebuttal arguments regarding the analogy of the disorders taught in the prior arts and the disorders in the claims are improper. Specifically, the scope of the disorders disclosed in the prior art, and claimed in instant invention, are not those presented in appellants arguments. Gregory teaches cyclooxygenase-2 inhibitors are known to be useful for treating human subject susceptible to or afflicted with autoimmune disease and inflammatory diseases, including liver transplant and biliary cirrhosis (not only primary cirrhosis as argued by appellant). The disorders encompassed in instant claims including alcoholic liver injury, which would read on alcoholic hepatitis (inflammation) and cirrhosis. (see Merck Manual, Home edition, page 621). Possessing the knowledge that cyclooxygenase-2 inhibitor is useful for treating inflammatory diseases generally and biliary cirrhosis specifically, an inflammatory liver disorder, one of ordinary skill in the art would have reasonable expected that cyclooxygenase-2 inhibitor would be useful for treating hepatitis, an inflammatory liver disorder. Further, the claimed compounds, old and well-known cyclooxygenase-2 inhibitor would have been reasonably expected to be useful for treating cirrhosis caused by alcohol since cyclooxygenase-2 inhibitor is generally known to be useful for treating biliary cirrhosis.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

Shengjun Wang  
Examiner  
Art Unit 1617

October 7, 2002

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